



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,080	08/30/2001	Carlo Effenhauser	RDID01056US	7687

7590 06/06/2003

Roche Diagnostics Corporation
9115 Hague Road, Bldg. D
P.O. Box 50457
Indianapolis, IN 46250-0457

EXAMINER

WINGOOD, PAMELA LYNN

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 06/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/943,080	Applicant(s) Effenhauser et al.
Examiner Pamela Wingood	Art Unit 3736



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on _____.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-12 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-12 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____

2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 6) Other: _____

Art Unit: 3736

DETAILED ACTION

Drawings

1. The drawings are objected to because In Figure c, the hidden lines to illustrate the channel length as the disclosure suggests P. 14, at the first full paragraph. Furthermore, the views of Fig. 1 should be properly marked in accordance with MPEP. 608.02(u)(1) A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

2. Applicant is reminded of the proper language and format for an abstract of the disclosure. The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Art Unit: 3736

3. The abstract of the disclosure is objected to because it is not in a single paragraph and it exceeds the numerical word limitation. Correction is required. See MPEP § 608.01(b).

4. Regarding, Claim 1, there is a lack of antecedent basis for "proximal end of the elongate capillary structure" so I suggest an amendment to remedy this matter.

Claim Objections

5. Claim 4 is objected to because of the following informalities: Please remove the parentheses or parenthetic information. Appropriate correction is required.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-4,5, 6-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garcia (4,637,403) in view of Smart et al. (US 2002/0137998) and Mauze et al.

Garcia et al. discloses a glucose monitoring system having a driving unit (174, 150, 136) that has holder at the bottom- most portion of element (136) that is moved from a first to a second position after activation by pressing of the element with a spring (Col. 9, lns. 45-55), and an enclosed disposable unit with a holding area (upper portion of 180) such that they are integral

Art Unit: 3736

(Fig. 6, Col. 10, Ins.1-5). Further, there is a narrow capillary channel structure (183) that uses suction to draw the fluid to the diagnostic area, a detection zone (172) that is porous (Col. 9, Ins. 55-62), and in an alternative embodiment (Col. 12, Ins. 15-25) a needle that is retracted halfway to withdraw fluid ;however, there is not at least one capillary channel open to the outside along a longitudinal extension of the capillary structure.

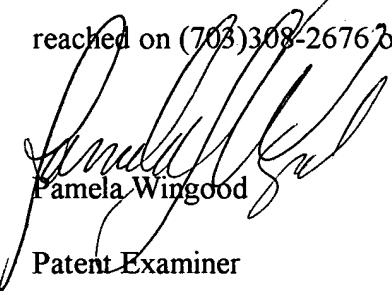
Smart et al. (US 2002/0137998) discloses an integrally manufactured silicon microprobe with holding areas at pads (Fig. 2a), with an integrated biosensor having a V-shaped channel along the length, with the length of .5mm-2.5mm (p. 3, [0091]) in an analogous art for the purpose of assisting in fluid collection.

Mauze et al. discloses a diagnostic blood collection device having a capillary channel in an analogous art for the purpose of the showing the combination a suction and capillary force in single diagnostic device and a cross-section range. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the needle of Garcia et al. as shown by Smart et al and Mauze et al. because the channel along the longitudinal length of the device would assist in drawing the fluid up the needle shaft by capillary action and the silicon material is a very effective material to be used because the etching and chemical processes can inexpensively and accurately make very small channels (p. 1 at [0013] and p.4 at [0097] with small lengths to limit the pain to the individual (p. 1 at [0013]) and the combination of a device using suction and capillary forces is provided by Mauze (Col. 3, Ins. 35-39 and Col. 1, Ins. 45-51) to take a small and very rapid blood sample and diagnostic measurement of limit the amount of

Art Unit: 3736

pain to the subject (Col. 1, lns. 45-50). Regarding Claim 5, the motivation to modify the embodiment of Fig. 6 by retracting the capillary structure slightly is shown at (Garcia at Col. 12, lns. 20-25) to allow fluid to collect at the location. The slight differences in cross-section and length from the prior art and the claimed device are design choices that is not inventive and within the range of one of ordinary skill in the art *In re Rose, 105 USPQ 237 (CCPA)*.

Any question regarding this application can be addressed to Pamela Wingood who can be reached on (703)308-2676 on Monday-Thursday and alternate Fridays from 7:30-5:00pm.


Pamela Wingood

Patent Examiner

May 17, 2003